No. 24-1714

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TRANSGENDER AMERICAN VETERANS ASSOCIATION,

Petitioner,

v.

SECRETARY OF VETERANS AFFAIRS,

Respondent.

On Petition to the Federal Circuit

BRIEF FOR RESPONDENT

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STATEMENT OF RELATED CASES

The government is not aware of any related cases within the meaning of Federal Circuit Rule 47.5(a). Two previous actions relating to the same petition for rulemaking at issue here were voluntarily dismissed in 2018 and 2024. *See Fulcher v. Secretary of Veterans Affairs*, No. 17-1460 (Fed. Cir.) (dismissed Aug. 1, 2018); *In re Transgender Am. Veterans Ass'n*, No. 24-108 (Fed. Cir.) (dismissed Mar. 5, 2024).

STATEMENT OF JURISDICTION

This Court has jurisdiction pursuant to 38 U.S.C. § 502 over the petition challenging the decision of the Secretary of Veterans Affairs to deny petitioner's rulemaking request.

STATEMENT OF THE ISSUE

Petitioner Transgender American Veterans Association filed a petition for rulemaking with the Secretary of Veterans Affairs requesting that the agency amend its regulations to provide coverage for gender affirming surgical care. In February 2024, the Secretary denied the rulemaking request, explaining that the agency was "consider[ing] how and when it might ultimately provide gender affirming surgery," but that it was "not ready at this time to initiate a rulemaking addressing the specific regulatory changes proposed in the petition." Appx001-002. The Secretary explained that, among other things, the agency needed to evaluate whether its prior proposal to amend the relevant regulation and associated economic analyses "must be updated" in light of the significant expansion of coverage brought on by the expedited implementation of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022. Appx001.

The question presented is whether, under this Court's highly deferential standard of review for an agency's denial of a petition for rulemaking, the Secretary's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

STATEMENT OF THE CASE

A. Legal Background

1. Congress tasked the Secretary of Veterans Affairs with providing health care services to the nation's veterans. The Secretary exercises considerable discretion in carrying out that task. For certain veterans, such as those with a service-connected disability, the Secretary "shall furnish hospital care and medical services which the Secretary determines to be needed." 38 U.S.C. § 1710(a)(1)-(2). For other eligible veterans, the Secretary may "furnish hospital care [and] medical services ... which the Secretary determines to be needed" "to the extent resources and facilities are available." *Id.* § 1710(a)(3).

The Secretary has promulgated comprehensive regulations to implement the statutory mandate. *See* 38 U.S.C. § 501(a) (granting the Secretary rulemaking authority). As relevant here, the Secretary provides enrolled veterans with "hospital, outpatient, and extended care services" covered by the "medical benefits package." 38 C.F.R. § 17.38; *see also id.* § 17.36 (enrollment requirements). The medical benefits package generally covers inpatient and outpatient medical, surgical, and mental health care. *Id.* § 17.38(a)(1)(iii), (2)(i).

The medical benefits package also excludes coverage for certain care. See 38 C.F.R. § 17.38(c). From its inception, the package has excluded coverage for "[g]ender alterations." Id. § 17.38(c)(4); see Enrollment—Provision of Hospital and Outpatient Care to Veterans, 64 Fed. Reg. 54,207, 54,218 (Oct. 6, 1999). In light of that

exclusion, the Secretary provides all needed "gender-affirming care"—including hormone therapy and gender affirming prosthetics—"except gender affirming surgical procedures." U.S. Dep't of Veterans Affairs, *Gender-Affirming Care at VA:* Resource for Veterans (June 2024), https://perma.cc/R8ZD-8KBF. Veterans seeking such surgical interventions may obtain them outside the Veterans Affairs (VA) health care system.

Veterans may challenge an individual coverage decision—including the denial of gender affirming care—through the administrative and judicial review process established to adjudicate veterans' benefits claims. Before the agency, the process is intended to be non-adversarial. See 38 U.S.C. § 5103 et seg.; 38 C.F.R. § 3.103(a). A veteran dissatisfied with VA's initial resolution of a claim may appeal the decision to the Board of Veterans' Appeals, an administrative body with authority to review questions of law and fact affecting veterans' benefits. 38 U.S.C. § 7104(a). The Board's decisions are subject to judicial review in the U.S. Court of Appeals for Veterans Claims, an independent Article I judicial body with authority to review legal and factual issues decided by the agency. *Id.* §§ 7252, 7261(a). Legal determinations by the Court of Appeals for Veterans Claims then may be appealed to the U.S. Court of Appeals for the Federal Circuit, which is authorized to "decide all relevant questions of law, including interpreting constitutional and statutory provisions." *Id.* § 7292(d)(1); see also id. § 7292(a), (c); Szemraj v. Principi, 357 F.3d 1370, 1375 (Fed. Cir. 2004). Further review may be sought in the Supreme Court. 38 U.S.C. § 7292(c).

2. In 2022, Congress enacted the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022. See Pub. L. No. 117-168, 136 Stat. 1759 (PACT Act). Among other things, the PACT Act "[e]xpands and extends eligibility for VA health care for Veterans with toxic exposures and Veterans of the Vietnam, Gulf War, and post-9/11 eras." U.S. Dep't of Veterans Affairs, The PACT Act and Your VA Benefits, https://perma.cc/AQM7-S6Q2. In particular, the Act extends the timeline for veterans to enroll postdischarge, recognizes additional grounds for enrollment eligibility, and expands specific qualifying service locations. See PACT Act, § 103, 136 Stat. at 1762-63 (establishing expansion). As a result, "all Veterans who served in the Vietnam War, the Gulf War, Iraq, Afghanistan, the Global War on Terror, or any other combat zone after 9/11" as well as "Veterans who never deployed but were exposed to toxins or hazards while training or on active duty in the United States" are "eligible to enroll in VA health care." Appx555. The PACT Act makes those veterans eligible for hospital care, medical services, and nursing home care. 38 U.S.C. § 1710(e)(1)(G)-(I).

The PACT Act "is perhaps the largest health care and benefit expansion in VA history." U.S. Dep't of Veterans Affairs, *The PACT Act and Your VA Benefits, supra.*In the first year of the Act's operation alone, nearly 114,000 veterans from the PACT Act population enrolled in VA health care, contributing to a significant increase in the total number of enrollees compared to previous years. *See* U.S. Dep't of Veterans Affairs, *One Year of the PACT Act: A Historic Expansion of Benefits and Health Care for*

Veterans and Their Survivors (Aug. 10, 2023), https://perma.cc/4BST-MCCW. To date, over 700,000 veterans have enrolled in VA health care since the PACT Act's enactment, a more than 34% increase in enrollees compared to before the Act's passage. See Hearing Before the Senate Comm. of Veterans' Affairs, at 4 (Sept. 18, 2024) (Statement of Mr. Joshua Jacobs and Dr. Shereef Elnahal), https://perma.cc/95CX-MWBP. And more than 840,000 additional veterans already enrolled in VA health care have experienced increased prioritization in their access to care as a result of the PACT Act. Id.

Given the significant size of the PACT Act's expansion of eligible beneficiaries, Congress authorized the Secretary to implement the extension of benefits to new categories of covered veterans in a phased approach. *See* 38 U.S.C. § 1710(e)(6)(A). Under this phased approach, VA's implementation of the PACT Act—and the associated expansion of benefits and care—would occur in two-year increments over a period of eight years. *Id.* Congress authorized the Secretary to "modify" the phased implementation "as the Secretary determines appropriate based on the number of veterans receiving" care and "the resources available to the Secretary." *Id.* § 1710(e)(6)(B)(i).

In November 2023, President Biden, in consultation with the Secretary, announced that VA would eliminate the "phased in-approach called for by the PACT Act." Appx555. President Biden announced that VA instead would allow all veterans made eligible for benefits by the PACT Act to enroll for coverage beginning in March

2024, making "millions of Veterans ... eligible for VA health care up to eight years earlier than written into law." Appx555. In accordance with the President's instructions, VA began accepting applications for enrollment from all veterans eligible for benefits pursuant to the PACT Act in March 2024. Appx555.

B. Prior Proceedings

- 1. Petitioner is Transgender American Veterans Association (TAVA), a membership organization that advocates on behalf of transgender veterans. Appx009. TAVA asserts that its members include transgender veterans who have been diagnosed with gender dysphoria. Appx009. TAVA further asserts that although its members have been provided gender affirming care by VA related to their diagnoses, those "who have sought sex reassignment surgery through the VA, or coverage of such surgery by the VA, have been denied such surgery or coverage because of the existing regulatory exclusion of 'gender alterations' from covered benefits." Appx009; see also Appx010-011. TAVA does not state whether any of its individual members sought review of any coverage decision through VA's administrative and judicial review process.
- 2. In May 2016, TAVA filed a rulemaking petition with the Secretary requesting that the agency "amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4) ..., that exclude medically necessary sex reassignment surgery for transgender veterans from the medical benefits package." Appx005. The petition further requested that the Secretary "promulgate regulations expressly including

medically necessary sex reassignment surgery for transgender veterans in that medical benefits package." Appx005. The petition asserted that the exclusion is "arbitrary and capricious" and "violate[s] the Equal Protection component of the Fifth Amendment." Appx006, Appx032.

Over the course of 2016, the Secretary drafted a regulatory proposal to revise the gender alterations exclusion and performed an initial impact analysis of the proposal. *See* Appx078. But the Secretary ultimately declined to issue a notice of proposed rulemaking that year.

In January 2017, TAVA and two individual veterans filed a petition for review with this Court. *See Fulcher v. Secretary of Veterans Affairs*, No. 17-1460 (Fed. Cir.). The petitioners asserted that the Secretary's failure to move forward with the proposed rulemaking in 2016 amounted to a constructive denial of their petition for rulemaking. Alternatively, the petitioners argued that the agency had unreasonably delayed acting on the rulemaking request. In July 2018, while the matter was pending before this Court, the Secretary published a notice in the Federal Register soliciting comments on TAVA's petition for rulemaking. 83 Fed. Reg. 31,711 (July 9, 2018). Following publication of that notice, TAVA and the other plaintiffs voluntarily dismissed the pending petition for review. Appx321.

3. In June 2021, after reviewing the various comments generated by the Federal Register notice, the Secretary initiated a renewed rulemaking effort. The Secretary announced that the agency was "taking the first necessary steps to expand"

VA's care to include gender confirmation surgery." Appx161. In accompanying guidance, the Secretary explained that the agency was "reviewing its policies," including evaluating "statutory and regulatory requirements to build out a continuum of care that provides all medically necessary services for our transgender and gender diverse Veterans." Appx327.

The Secretary cautioned that the agency was taking a methodical approach to the development of its regulatory proposal. Such an approach was appropriate, the Secretary explained, to ensure alignment "with current Administration priorities, best medical practice, research, and professional health organizations." Appx327. The Secretary further explained that proceeding methodically was necessary to "develop processes to meet the surgical and care coordination needs so that Veterans have clear and consistent access nationwide," Appx328, which "would enable a safe, coordinated continuum of care that is Veteran-centric," Appx327. The Secretary acknowledged that the process would "take time," but explained that the agency was "moving ahead." Appx161.

Since then, the Secretary has taken a number of actions in connection with the proposed rulemaking. The Secretary conducted a review of existing policies as well as statutory and regulatory requirements related to the provision of care to transgender veterans. The Secretary then drafted a rule that proposed to remove the gender alterations exclusion in the medical benefits package. Appx163. Because the proposal was designated a "significant" regulatory action pursuant to Executive Order 12,866,

the proposal was subject to internal governmental review, including as conducted through the Office of Information and Regulatory Affairs (OIRA). Appx164; *see also* Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993). The proposal remains under review with VA, which is continuing to consider relevant information.

Among other things, the Secretary has called for further review of the proposed new rule in light of the PACT Act's coverage expansion. In February 2024, following the announcement of the Act's expedited implementation, the Secretary requested an analysis of the potential impact of the expansion on the agency's prior proposal to revise the medical benefits package. Appx442. The Secretary explained that the "influx of new patients" into VA's health system as a result of the PACT Act's expedited implementation "has the potential to change how, where, and at what cost VA provides health care." Appx442. The Secretary noted that "prior analyses" of the proposal "to remove the gender alteration exclusion have not considered or addressed the PACT Act's expansion of eligibility." Appx442.

The Secretary thus directed VA staff to collect additional data and conduct further studies related to the proposal. Among other things, the Secretary requested data on the "number of trans-Veterans who sought care or service through [VA] since 2016," "the population of Veterans who will be newly eligible for care and services under" the PACT Act, and "the number of Veterans who became newly eligible for care and services" under the PACT Act "who would require gender affirming surgery if offered" by VA. Appx442-443 (emphasis omitted). The Secretary also requested

an analysis of "how many transgender veterans" would be required to travel if surgeries were "only offered at specific surgery centers" and whether veterans would be eligible for benefits to cover such travel under the VA's "Beneficiary Travel" program. Appx443 (explaining that "VA has not yet examined or analyzed how many transgender Veterans would in fact be eligible" for Beneficiary Travel benefits). Similarly, in light of the "complex and specialized determination of a patient's clinical requirement for gender affirming surgery," the Secretary requested an analysis of "whether a unique clinical appeals process for gender affirming surgery is necessary or warranted" and, if so, directed VA staff to "design that process." Appx443. And the Secretary instructed VA staff to determine if the notice of proposed rulemaking or regulatory impact analysis previously submitted to OIRA "must be updated in light of these estimates, data, and analyses." Appx443.

4. In January 2024, TAVA filed a petition with this Court, seeking a writ of mandamus to compel the Secretary to act on its rulemaking petition. *See In re Transgender Am. Veterans Ass'n*, No. 24-108 (Fed. Cir.). In February 2024, the Secretary denied TAVA's rulemaking request. Appx002.

In the February 2024 denial letter, the Secretary explained that "VA remains committed to providing care to transgender Veterans and will continue to take steps to consider any potential changes to the provision of medical care to that important population." Appx001. But the Secretary explained that any "potential change in coverage ... must be implemented in a manner that has been thoroughly considered

and ensures that the services made available to Veterans meet VA's rigorous standards for consistent and quality health care nationwide." Appx001. In particular, the Secretary explained that, among other considerations, the agency would be "produc[ing] estimates and collect[ing] data concerning the population of Veterans who will become newly eligible" for benefits under the PACT Act, which will "inform further analyses, including whether the Notice of Proposed Rulemaking or Regulatory Impact Analysis VA previously produced must be updated and submitted" for further OIRA review. Appx001. Because the VA was "not ready at this time to initiate a rulemaking addressing the specific regulatory changes proposed in the petition," the Secretary "denie[d] the petition for rulemaking to repeal or amend 38 C.F.R. § 17.38(c)(4)." Appx001.

In light of the Secretary's final action on the rulemaking petition, TAVA voluntarily dismissed its mandamus petition. Order, *In re Transgender Am. Veterans Ass'n*, No. 24-108 (Fed. Cir. Mar. 5, 2024), Dkt. No. 55.

5. In April 2024, TAVA filed this action challenging the Secretary's denial of the rulemaking request. Petition for Review (Apr. 19, 2024) (Pet.). TAVA argued that the denial was arbitrary and capricious, asserting that the Secretary "failed to offer reasoned explanation and adequate justification for the denial" of the rulemaking petition. Pet. 5. TAVA characterized the Secretary's proffered reasons related to the PACT Act's implementation as "insufficient." Pet. 5. TAVA also asserted that the denial "impermissibly discriminat[ed] on the basis of sex and transgender status" in

Process Clause" and "Section 1557 of the [Affordable Care Act]." Pet. 5-6 (citing 42 U.S.C. § 18116(a)). As to the requested relief, TAVA asked the Court to "direct VA to undertake rulemaking to amend or repeal its regulations ... that exclude medically necessary gender-confirmation surgery from the medical benefits package." Pet. 6.

SUMMARY OF ARGUMENT

This Court's review of the Secretary's denial decision is exceedingly narrow. It requires only that the Secretary adequately explained the reasons for the decision and that the explanation has some basis in the record.

The Secretary easily cleared that low bar in denying the rulemaking request. The Secretary explained that the agency remains committed to providing gender affirming care to veterans and is continuing to evaluate how and when it will provide gender affirming surgery for certain veterans. But the Secretary explained that the agency was not ready "at this time" to adopt the "specific regulatory changes proposed" by TAVA, Appx001, given the need for continued evaluation of this important change in coverage, particularly in light of the PACT Act's significant and expedited expansion of the number of veterans eligible to receive health care benefits from the agency. The Secretary's explanation finds ample support in the record: The PACT Act is perhaps the largest health care expansion in VA history and could affect "how, where, and at what cost" the agency provides health care, including gender affirming surgery. Appx442.

TAVA's objections to the denial rest on inaccurate characterizations of the Secretary's decision. The Secretary never suggested that the agency was abandoning its rulemaking efforts or was "too busy" implementing the PACT Act. Pet'r Br. 28. Nor did the Secretary question the need or effectiveness of gender affirming surgery for certain veterans. Instead, the Secretary reasonably explained that additional analysis was required to determine whether the agency's proposal to amend the gender alterations exclusion "must be updated," and that the agency was not prepared in February 2024 to initiate such a rulemaking. Appx001. As to the Secretary's actual justification for denying the rulemaking request, TAVA offers no reason to question the decision to undertake further study before moving forward with a significant proposed change to the medical benefits package.

The other arguments TAVA offers for why the denial was arbitrary and capricious are equally unavailing. The Secretary reasonably sought additional information in early 2024 in light of the PACT Act's expedited implementation, which TAVA concedes "dramatically" accelerated the Act's substantial expansion of eligible beneficiaries. Pet'r Br. 30. Moreover, the considered approach taken here was not arbitrary simply because in a different context the Secretary proceeded in an expedited manner to secure protections for reproductive health services in the immediate wake of *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022). And the fact that the Secretary declined to adopt TAVA's preferred approach on TAVA's preferred

timeline does not undermine the reasonableness of the approach the Secretary actually undertook.

TAVA is also incorrect that the denial contravened the antidiscrimination principles of the Fifth Amendment and Section 1557 of the Affordable Care Act. TAVA offers no meaningful argument as to how the facially neutral denial of the petition was discriminatory. Instead, TAVA's argument is that the operation of the gender alterations exclusion violates the Fifth Amendment and Section 1557. But that is not the relevant inquiry. The Secretary did not rest the denial decision on any view as to the constitutionality or lawfulness of the existing exclusion. Rather, the Secretary denied the rulemaking request based on the need for further study of the revised regulation's economic impact and the agency's ability to implement the revised regulation. The only question before this Court is whether the Secretary's narrow and fact-bound explanation for the denial of the rulemaking request was reasonable—a standard the Secretary's explanation more than satisfied. Veterans wishing to challenge the operation of the gender alterations exclusion may do so by seeking review of individual coverage decisions through the administrative and judicial review process established to adjudicate veterans' benefits claims.

Finally, TAVA's requested remedy—an order directing the Secretary to undertake rulemaking—is overbroad. If the Court finds the denial of the rulemaking request invalid, it should follow the "ordinar[y]" course and remand to the Secretary for the agency to "reconsider its denial of the petition, in light of the correct

interpretation of the law as enunciated by the court." American Horse Prot. Ass'n v. Lyng, 812 F.2d 1, 7 (D.C. Cir. 1987) (quotation marks omitted).

ARGUMENT

I. Standard of Review.

This Court "review[s] the VA's denial of a rulemaking petition to determine whether the denial was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Military-Veterans Advocacy Inc. v. Secretary of Veterans Affairs, 38 F.4th 154, 160 (Fed. Cir. 2022) (quoting 5 U.S.C. § 706(2)(A)); see also 38 U.S.C. § 502. This "highly deferential standard is rendered even more deferential by the treatment accorded by the courts to an agency's rulemaking authority." Military-Veterans Advocacy, 38 F.4th at 160 (quotation marks omitted). Where "a proposed rulemaking pertains to a matter of policy within the agency's expertise and discretion," this Court's review is "narrow" and "limited to ensuring that the agency has adequately explained the facts and policy concerns it relied on and to satisfy [the court] that those facts have some basis in the record." Id. (quotation marks omitted). Accordingly, "[o]verturning an agency's judgment not to institute rulemaking is appropriate in only the rarest and most compelling of circumstances." Id. (quotation marks omitted); see Service Women's Action Network v. Secretary of Veterans Affairs, 815 F.3d 1369, 1376 (Fed. Cir. 2016) (same).

II. The Secretary Lawfully Denied TAVA's Rulemaking Request.

- A. The Secretary's Denial of the Petition Was Reasonable.
- 1. The Secretary's denial of TAVA's rulemaking request satisfied this Court's deferential standard for reasoned decision making. At the outset, the Court's review of the Secretary's decision is "narrow" and "limited" because whether to institute a rulemaking to amend the medical benefits package "pertains to a matter of policy within" the Secretary's "expertise and discretion." Military-Veterans Advocacy, 38 F.4th at 160 (quotation marks omitted). Congress delegated to the Secretary discretionary authority over the provision of health care services to the nation's veterans. See 38 U.S.C. § 1710(a)(1) (providing that the Secretary must furnish hospital care and medical services "which the Secretary determines to be needed" (emphasis added)); see also id. § 1710(a)(2), (3), (b)(1), (c) (similar). And the Secretary enjoys broad rulemaking authority "to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department." *Id.* § 501(a). Thus, whether, how, and at what time to amend the gender alterations exclusion are matters firmly committed to the Secretary's discretion.

The Secretary reasonably exercised that discretionary authority in denying TAVA's rulemaking request. The Secretary explained that "VA remains committed to providing care to transgender Veterans." Appx001. The Secretary pointed out that VA not only "presently provides" a range of gender affirming care, but also is evaluating proposals to repeal or amend the gender alterations exclusion. Appx001.

To that end, the Secretary previously submitted a notice of proposed rulemaking and regulatory impact analysis for review to OIRA and is "continu[ing] to consider how and when [VA] might ultimately provide gender affirming surgery." Appx001-002; see also Appx163-164.

The Secretary explained, however, that "VA is not ready at this time to initiate a rulemaking addressing the specific regulatory changes proposed in [TAVA's] petition" because the matter is still under consideration with the agency. Appx001. The Secretary explained that "VA has moved methodically in its consideration of this important potential change in coverage because it must be implemented in a manner that ... ensures that the services made available to Veterans meet VA's rigorous standards for consistent and quality health care nationwide." Appx001. Among other things, the Secretary explained that the agency was "produc[ing] estimates and collect[ing] data concerning the population of Veterans who will become newly eligible" for care pursuant to the PACT Act. Appx001. The Secretary further explained that "[t]hese estimates and data" may affect whether the prior proposed rule and regulatory analysis "must be updated." Appx001.

The Secretary's explanation was reasonable and finds ample support in the record. As explained, the PACT Act "is perhaps the largest health care and benefit expansion in VA history." U.S. Dep't of Veterans Affairs, *The PACT Act and Your VA Benefits, supra.* The Act makes a host of veteran populations eligible for VA health care for the first time, including "Veterans with toxic exposures" and certain

"Veterans of the Vietnam, Gulf War, and post-9/11 eras." *Id.*; *see* 38 U.S.C. § 1710(e)(6)(A). In the first year alone, the PACT Act resulted in nearly 114,000 new enrollees in VA health care. *See supra* p. 4. So far, over 700,000 veterans have newly enrolled in VA health care since the PACT Act's enactment, and another 840,000 already enrolled veterans have experienced increased prioritization in their access to care as a result of the Act. *See supra* p. 5.

Moreover, the pace of the PACT Act's expansion of benefits changed dramatically in March 2024. Originally, the number of veterans eligible for care and the agency's responsibility for providing care to those veterans would have increased gradually over a period of eight years. But the PACT Act's expedited implementation required the agency to provide care to all newly eligible veterans beginning in March 2024, only 18 months after the Act's enactment. The modification to the Act's staggered enrollment made "millions of Veterans ... eligible for VA health care up to eight years earlier than written into law." Appx555.

In light of the PACT Act's dramatic expansion in coverage and its expedited implementation, the Secretary sought additional information on the expansion's potential impact on the agency's prior proposal to repeal or amend the gender alterations exclusion. "[P]rior analyses" of the proposal had not "considered or addressed the PACT Act's expansion of eligibility." Appx442. The Secretary thus sought data regarding, among other things, "the population of Veterans who will be newly eligible for care and services under" the PACT Act and the number of such

veterans "who would require gender affirming surgery if offered." Appx442 (emphasis omitted). Prior analyses also had not addressed "how many transgender veterans" would be required to travel if surgeries were "only offered at specific surgery centers." Appx443. Nor had they considered "whether a unique clinical appeals process for gender affirming surgery is necessary or warranted." Appx443. When faced with such uncertainty, it was reasonable for the Secretary to decline to move forward with TAVA's rulemaking request "at th[e] time." Appx001. The Secretary's decision to seek additional information about an important change in coverage falls considerably short of those "rare[] and most compelling of circumstances" in which it is "appropriate to overturn an agency judgment not to institute a rulemaking." Service Women's Action Network, 815 F.3d at 1375 (quotation marks omitted).

2. TAVA asserts that the Secretary's explanation for denying the rulemaking request was "disingenuous" and "inconsistent with VA's previous and concurrent actions" related to the PACT Act's implementation Pet'r Br. 27, 28. That assertion lacks merit.

Many of TAVA's arguments rest on incorrect characterizations of the Secretary's explanation for denying the rulemaking request. The Secretary never suggested that he denied the request because the agency was simply "too busy

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implementing the PACT Act." Pet'r Br. 28; see also Pet'r Br. 11.1 Instead, the Secretary explained that the agency was "not ready at this time to initiate a rulemaking" given the need for additional analysis regarding the effects of the PACT Act's expedited implementation on the draft proposed rule. Appx001. As explained, that explanation finds ample support in the record, which refutes TAVA's claim that the Secretary's justification amounts to no more than "an excuse to delay access," Pet'r Br. 12.

Indeed, as to the Secretary's actual explanation for denying the rulemaking request, TAVA has very little to say. TAVA does not dispute that the PACT Act effected a dramatic expansion in coverage for veterans. See Pet'r Br. 28. (recognizing that the statutory expansion was "significant"). Nor does TAVA dispute that the expansion may "change how, where, and at what cost VA provides health care," including the potential provision of gender affirming surgery. Appx442. In fact, TAVA recognizes that the "agency's obligations under the PACT Act" pose "potential cost increases." Pet'r Br. 42. TAVA also does not dispute that prior regulatory analyses had not addressed important questions related to the rulemaking, including what the impact of the PACT Act's expansion would be on the proposed

¹ Even if that were the justification, it is reasonable for an agency to deny a rulemaking petition due to a lack of necessary resources to engage in rulemaking. *See e.g.*, *Compassion Over Killing v. U.S. Food & Drug Admin.*, 849 F.3d 849, 855-56 (9th Cir. 2017) (upholding a denial of rulemaking in light of the agency's "limited" resources and "numerous statutory requirements for rulemaking").

rule and whether a unique clinical appeals process would be warranted. Appx443. And TAVA admits that the "nature of [the] PACT Act's implementations changed dramatically" between November 2023 and March 2024. Pet'r Br. 30. TAVA thus offers no reason to doubt the Secretary's conclusion that additional analysis was warranted to determine whether the agency's draft proposed rule and prior submissions to OIRA "must be updated." Appx001.

TAVA nonetheless argues that the denial was "inconsistent with," and an "abrupt course reversal" from, the Secretary's prior statements and actions related to the proposed revision of the gender alterations exclusion. Pet'r Br. 11, 29. But that too is premised on an incorrect description of the Secretary's denial decision. The Secretary never suggested that the agency was abandoning its rulemaking efforts; to the contrary, the Secretary made clear that the agency was "tak[ing] steps" to determine "how and when it might ultimately provide gender affirming surgery." Appx001-002. Far from demonstrating any "[i]nconsistency," Pet'r Br. 33, the Secretary's decision to deny the rulemaking request because of the need for additional analysis reflects the agency's "methodical[] ... consideration of this important potential change." Appx001. Since 2021, the Secretary has made clear that while the agency is "moving ahead" with the rulemaking, the process would "take time." Appx161. The methodical approach was necessary to "develop processes to meet the surgical and care coordination needs so that Veterans have clear and consistent access nationwide," Appx328, which "would enable a safe, coordinated continuum of care

that is Veteran-centric," Appx327. It was entirely consistent for the Secretary to continue moving forward in this considered manner, while declining to adopt the "specific regulatory changes proposed in [TAVA's] petition" at this time." Appx001.

TAVA suggests that because the PACT Act went into effect in August 2022, the Secretary "had time and opportunity to assess and incorporate the impact of the PACT Act." Pet'r Br. 33. But as TAVA itself recognizes, "the nature of [the] PACT Act's implementation changed dramatically" in the lead up to March 2024, Pet'r Br. 30, which is when the Secretary sought additional information regarding the effect of the Act's expedited implementation on the draft regulatory proposal. TAVA's argument also disregards the "broad discretion" the Secretary enjoys "to carry out [his] delegated responsibilities," *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007), including how and in what manner to evaluate the effect of intervening changes of law on proposed rulemakings.

TAVA likewise errs in suggesting that the Secretary's promulgation of a separate rule extending coverage for abortions in certain circumstances rendered "this denial arbitrary and capricious." Pet'r Br. 30 (citing Reproductive Health Services, 89 Fed. Reg. 15,451 (Mar. 4, 2024)). While the Secretary generally must treat like situations alike, see SKF USA Inc. v. United States, 263 F.3d 1369, 1382 (Fed. Cir. 2001), TAVA fails to explain how the finalization of an interim rule related to reproductive health services warrants the same treatment as the Secretary's ongoing consideration of potential amendments to the gender alterations exclusion. The Secretary promulgated

the abortion-related protections in the reproductive health rule following the Supreme Court's landmark decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022). *See Reproductive Health Services*, 87 Fed. Reg. 55,287 (Sept. 9, 2022) (interim final rule). The Secretary issued an interim rule on an expedited timeline due to the rapidly changing legal landscape, in which veterans who previously "could access abortions in their communities ... were losing access to such medical care." 89 Fed. Reg. at 15,453 (citation omitted); *see also* 87 Fed. Reg. at 55,288 (discussing changing legal landscape). The interim rule went into effect immediately, 87 Fed. Reg. at 55,296, meaning the Secretary had reliable data regarding the rule's effect on the provision of care when finalizing it eighteen months later. Against that backdrop, the Secretary reasonably finalized the interim rule's important protections without conducting additional analysis related to the PACT Act.

The Secretary's decision to take a different approach to address a different problem arising in a different context does not render the Secretary's decision to take a more measured approach regarding the gender alterations exclusion arbitrary and capricious. *Contra* Pet'r Br. 30-31. Nor was the Secretary required to spell out the reasons for that differential treatment in the denial, which required only an explanation of "the facts and policy matters underlying the decision," *Service Women's Action Network*, 815 F.3d at 1375; *see also Flyers Rights Educ. Fund, Inc. v. FAA*, 864 F.3d 738, 746 (D.C. Cir. 2017) ("[T]he record needed to support an agency's decision not to engage in rulemaking can be sparser than that needed to support rulemaking.").

3. TAVA's other arguments for why the denial was arbitrary and capricious fare no better. Pet'r Br. 15-27. TAVA again misapprehends the nature and reasoning of the denial in asserting that it conflicts with the statutory instruction to "furnish hospital care and medical service which the Secretary determines to be needed." 38 U.S.C. § 1710(a)(1); see Pet'r Br. 15-18. The Secretary reiterated in denying the rulemaking request that gender affirming care—including surgical care—"should be available to any Veteran who needs it." Appx001. But nothing compelled the Secretary to adopt "the specific regulatory changes proposed in [TAVA's] petition" "at th[e] time" simply because the agency broadly agrees as to the necessity of gender affirming surgery for certain veterans. Appx001. Determining how and when to provide such services is a "matter of policy" that the statutory scheme leaves to "the agency's expertise and discretion." Military-Veterans Advocacy, 38 F.4th at 160 (quotation marks omitted). Among other things, the Secretary is still evaluating whether the provision of gender affirming surgery would require an expansion of coverage for beneficiary travel and a unique clinical appeals process. Appx443. Given those ongoing considerations, the Secretary did not act arbitrarily or contravene the statute by declining to adopt the approach and timeline offered by TAVA's petition.

For much the same reason, it makes no difference to the Court's analysis here that the Secretary provides other forms of gender affirming care to veterans, Pet'r Br. 15-18, or that there is a "consensus on the effectiveness" of gender affirming surgical

interventions, Pet'r Br. 23. The Secretary's denial of the rulemaking request was not premised on a contrary view as to the need or effectiveness of gender affirming surgical interventions for certain veterans. The Secretary's denial decision rested on a narrow disagreement with TAVA regarding how best and on what timeline to provide those services, particularly in light of the ongoing uncertainty engendered by the expedited implementation of the PACT Act's expansion in coverage. As explained, TAVA hardly engages with that reasoning; instead, it challenges arguments that the Secretary neither offered nor relied upon in rejecting the rulemaking request.

At bottom, TAVA objects that the Secretary did not adopt its preferred timeline for, and approach to, amending the medical benefits package. The Secretary reasonably explained why he declined to do so, which is all that this Court requires when evaluating "an agency's judgment not to institute rulemaking." *Military-Veterans Advocacy*, 38 F.4th at 160. That TAVA would have preferred the Secretary to proceed in a different manner or at a different pace does not undermine the reasonableness of the approach the Secretary actually undertook. *See Service Women's Action Network*, 815 F.3d at 1376 (upholding the denial of a rulemaking petition even where "others may have determined that petitioners' requested rule [was] the best way" to address an issue, since that was "not the question before [the Court]").

B. The Secretary's Denial of the Petition Was Not Contrary to Law.

TAVA separately argues that the Secretary's denial of the rulemaking request contravened "the equal protection component of the Fifth Amendment" and "Section 1557 of the [Affordable Care Act]" because the denial amounted to prohibited discrimination on the basis of sex and transgender status. Pet'r Br. 50; see also Pet'r Br. 34-49. That argument also lacks merit.

1. The denial of the rulemaking petition itself does not constitute prohibited discrimination. The Fifth Amendment bars the federal government from drawing sex-based classifications that are not "substantially related to the achievement" of "important governmental objectives." *Berkley v. United States*, 287 F.3d 1076, 1082 n.1 (Fed. Cir. 2002) (quoting *United States v. Virginia*, 518 U.S. 515, 533 (1996)). And Section 1557 prohibits, as relevant here, "any health program or activity ... that is administered by an Executive Agency" from discriminating against an individual based on "ground[s] prohibited under" several other statutes, 42 U.S.C. § 18116(a), including Title IX's prohibition on discrimination "on the basis of sex," 20 U.S.C. § 1681(a).

The Secretary's denial of the rulemaking request does not run afoul of either prohibition on sex discrimination. The decision not to move forward with TAVA's proposal in February 2024 given the need for further analysis regarding the effects of the PACT Act's expedited implementation is "facially neutral" as to sex. *Service*

Women's Action Network, 815 F.3d at 1376. The denial neither draws any sex-based classifications nor discriminates against any protected individual by subjecting them to differential treatment on the basis of the individual's sex. See Muldrow v. City of St. Louis, 144 S. Ct. 967, 974 (2024) (defining "discrimination"). And although even facially neutral agency action may amount to intentional discrimination "if it was motivated by discriminatory animus," Service Women's Action Network, 815 F.3d at 1376 (quotation marks omitted), the Secretary's decision here plainly was not motivated by animus; TAVA does not even attempt to show that it was. Indeed, TAVA cites no example of a court holding that the mere denial of a rulemaking petition constitutes prohibited sex discrimination.

TAVA offers no meaningful arguments to the contrary. It suggests at one point that the denial "classifies on the basis of sex" because the "denial letter ... made specific reference to 'gender affirming surgery' and 'transgender veterans." Pet'r Br. 34. But TAVA quickly abandons that argument, and for good reason: The Secretary's denial does not draw sex-based classifications (or perpetuate sex-based discrimination) simply because the letter in which the decision was memorialized discusses issues related to transgender veterans. Otherwise, any agency action merely touching on issues related to "race, national origin or gender" would be subject to heightened scrutiny. *Berkley*, 287 F.3d at 1084 (quotation marks omitted). That is not the law.

2. Properly understood, TAVA's argument is that the operation of the gender alterations exclusion violates the Fifth Amendment and Section 1557,² not that the Secretary's denial of the rulemaking request was discriminatory. But the only agency action on review is the denial decision, and the only question before this Court is whether the Secretary "adequately explained" the reasons for the denial. *Military-Veterans Advocacy*, 38 F.4th at 160 (quotation marks omitted). As discussed, the Secretary reasonably explained the rationale for denying the rulemaking request.

Critically, no part of the Secretary's explanation turned on any view as to the requirements of the Fifth Amendment or Section 1557. Accordingly, TAVA's arguments that the operation of the gender alterations exclusion violates those provisions are "simply beside the point." *Military-Veterans Advocacy*, 38 F.4th at 161. Regardless of whether TAVA's arguments about the gender alterations exclusion have merit, the Secretary "did not rest [the] denial on any contrary understanding" of the Fifth Amendment or Section 1557. *Id.* Instead, the Secretary denied the request based on narrow and fact-bound considerations regarding the need for further review related to the PACT Act's expedited implementation. As TAVA recognizes, this Court's review is "limited to the explanations contained in the administrative record."

² TAVA did not argue that the gender alterations exclusion violated Section 1557 in its rulemaking petition, *see* Appx005-040, so any such argument here fails for the independent reason that it was not properly raised before the agency. *See Compassion Over Killing*, 849 F.3d at 857 (explaining that agency need only "indicate that it has considered the potential problem identified *in the petition*" (emphasis added)).

Pet'r Br. 41. And because TAVA made no showing that the Secretary's explanation "relied on an invalid directive," *Preminger v. Secretary of Veterans Affairs*, 632 F.3d 1345, 1354 (Fed. Cir. 2011) (per curiam), or "failed to comply with any particular legal requirement," TAVA "has not shown that the VA's decision was contrary to law," *Military-Veterans Advocacy*, 38 F.4th at 162 (emphasis omitted).

This Court's limited review of the Secretary's denial decision does not insulate the gender alterations exclusion from challenge. Individual veterans who have been denied gender affirming surgery or coverage for such surgery because of the exclusion may challenge the coverage decision through the VA's established administrative and judicial review process to adjudicate veterans' benefits claims. As explained, the scheme authorizes review of questions of law affecting veterans' benefits, including review in this Court to "decide all relevant questions of law, including interpreting constitutional and statutory provisions." 38 U.S.C. § 7292(d)(1); see also id. § 7292(a), (c). Thus, nothing prevents veterans from obtaining judicial review—including de novo review in this Court—of any claim that the gender alterations exclusion violates the Fifth Amendment or Section 1557. See Szemraj v. Principi, 357 F.3d 1370, 1372 (Fed. Cir. 2004) ("We review the appellant's claim of legal error in the decision of the Court of Appeals for Veterans Claims without deference."). In this posture, however, the Court's review of the denial is "extremely limited and highly deferential," Massachusetts, 549 U.S. at 527-28 (quotation marks omitted)—a standard the Secretary's explanation more than satisfied.

III. Any Relief Should Be Limited.

For the reasons explained above, TAVA's petition should be dismissed because the Secretary reasonably denied the rulemaking request. If this Court concludes otherwise, however, the proper remedy would be to remand to the Secretary "to require the agency 'to reconsider its denial of the petition, in light of the correct interpretation of the law as enunciated by the court." *American Horse Prot. Ass'n v. Lyng*, 812 F.2d 1, 7 (D.C. Cir. 1987) (quoting *WWHT*, *Inc. v. FCC*, 656 F.2d 807, 819 (D.C. Cir. 1981)); *see, e.g., Massachusetts*, 549 U.S. at 535 (remanding to the agency to reassess rulemaking petition); *Flyers Rights Educ. Fund*, 864 F.3d at 747 (same).

TAVA asks this Court to go further and "direct VA to undertake rulemaking to amend or repeal its regulations ... that exclude medically necessary gender-confirmation surgery from the medical benefits package." Pet. 6. But even where courts find an agency's denial of a rulemaking request invalid, they rarely "go further and order the [agency] to institute rulemaking." *Flyers Rights Educ. Fund.*, 864 F.3d at 747. That is because such a remedy is appropriate only in "limited" circumstances, such as where agencies face "statutorily imposed rulemaking requirements." *WWHT*, 656 F.2d at 819 & n.21; *Flyers Rights Educ. Fund.*, 864 F.3d at 747 (similar). No like circumstances are present here, as the Secretary enjoys broad delegated authority to determine how and in what matter to issue rules related to the provision of health care for veterans. TAVA provides no explanation for why deviating from the "ordinar[y]"

remedial course and ordering the Secretary to engage in rulemaking would be warranted here. *American Horse Prot. Ass'n*, 812 F.2d at 7.

CONCLUSION

For the foregoing reasons, the petition should be dismissed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 7,374 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

s/ David L. Peters

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CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ David L. Peters

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